REMARKS

Reconsideration of the present application, as amended, is respectfully requested.

A. Claim Amendments

Claims 1, 16 and 30 are amended, without prejudice, to more particularly set forth that which is claimed. Certain claims depending from these claims are amended to conform to the independent claims and/or to correct minor informalities. Withdrawn claim 30 and 33-35, although withdrawn, are amended in the event that these claims are rejoined to the claims under prosecution, as noted previously by the Examiner in the Office Action mailed on February 13, 2007, page 4. New dependent claims 38 and 39 are added to more particularly set forth that which Applicants consider to be their invention. New dependent claim 40 is also added to more particularly set forth that which Applicants consider to be their invention, but depends from claim 30, previously withdrawn. Withdrawn claims 36-37 are cancelled without prejudice. No new matter is added.

B. Rejection Under 35 U.S.C. 112, first paragraph

Beginning at page 2 of the Office Action, the Examiner has maintained the rejection of claims 1, 2, 4-17 and 19-29, again alleging that the claims do not fulfill the enablement requirement of 35 U.S.C., first paragraph. At pages 3-4 of the Office Action, the Examiner takes the position that the data provided by the instant patent application is insufficient because the several subject chimpanzees showed raised post-challenge HCV levels and are therefore insufficient to show that the vaccine prevents HCV infection. The Examiner also argues that since there is no existing vaccine to prevent HCV in humans, more evidence is needed for the instant claims to be patentable under 35 U.S.C. 112, first paragraph. The Examiner further argues that the granted U.S. patents cited by the Applicants do not actually claim an HCV vaccine. In this regard, the Examiner also argues that each patent application is examined on its own merits.

Applicants respectfully traverse this rejection. To begin, there are no claims currently under prosecution that claim a method of treating or preventing HCV. At best, the withdrawn claims (claim 30, *et seq.*), are directed to "[a] method of enhancing protective immunity to hepatitis C virus..." The Examiner is respectfully reminded that 35 U.S.C. 112, first paragraph,

requires that a patent application teach how to make and use the claimed invention. It does not require that more than one use be taught for a given claimed composition. The Examiner has argued that the specification and examples fail to confirm that the claimed vaccine prevents or treats hepatitis C infection, as such. However, Applicants urge that the patent application clearly teaches how to use the claimed vaccine to enhance protective immunity and thus limit or inhibit the development of chronic infection. It is submitted that nothing more is required, given the state of the art.

Applicants enclose copies of several references[1] as Exhibits A-E, which support Applicants' position that the application provides sufficient confirmation that the claimed vaccine is useful. A supplemental PTO Form 1449 listing Exhibits A-E as references is enclosed herewith for the convenience of the Examiner in checking off these references as made of record in the instant patent application.

Researchers have noted that it is very difficult to prevent substantial HCV infection. In particular, Farci *et al.* reported that HCV infection does not elicit protective immunity against re-infection with homologous or heterologous strains. This raised concerns for the development of effective vaccines against HCV (Farci P. *et al.*, *Science* 258:135-140, 1992, See Abstract, attached as Exhibit **A**). Thus, researchers who are developing vaccines against HCV focused their strategies to limit chronic infection rather than to prevent infection itself. Particularly, Lechmann *et al.* teaches that a vigorous multispecific cellular immune response is important in the resolution of infection, and sterilizing immunity may not be necessary if a vaccine can be developed to prevent chronic infection (Lechmann *et al.*, 2000, *Semin. Liver Dis.* 20(2):211-226, , See Abstract, attached as Exhibit **B**).

Lechner *et al.* teaches that cytotoxic T lymphocyte ("CTL") responses were more common in persons who had cleared viremia compared with those with persistent viremia, although the frequencies of HCV-specific CTLs were lower than those found in persons during and after resolution of acute HCV infection. This finding provides a rationale to explore immunotherapy as an adjunctive therapy in persons with chronic progressive HCV infection

[1] Ex. A: Farci, et al., 1992 "*Lack of Protective Immunity Against Reinfection with Hepatitis C*" *Virus Science* 258:135-140;
Ex. B: Lechmann, et al., 2000 "*Vaccine Development For Hepatitis C*" *Seminars In Liver Disease* 20(2):211-226;
Ex. C: Lechner et al., 2000 *J. Exp. Med.* 191(9): 1499-1512;
Ex. D. Bisceglie et al., 2002, "*New Therapeutic Strategies for Hepatitis C*," *Hepatology.* 35(1):224-231; and
Ex. E: Houghton et al., 2005 "*Prospects for a vaccine against the hepatitis C virus*" *Nature Insights*, 436:961-936.

(Lechner F. *et al.*, *J. Exp. Med.* 191: 1499-1512, See lines 41-50, right column, page 1509, attached as Exhibit **C**).

In addition, Bisceglie *et al.* teaches that, although the ultimate gosal of antiviral therapy for hepatitis C has long been the elimination of HCV from serum and liver during and after therapy, it must be recognized that it is not the viral infection *per se* that must be treated but the liver disease that results from chronic infection, and this recognition has led to consideration of therapies that are aimed at minimizing hepatic injury and fibrosis (Biscelglie *et al.*, 2002, *Hepatology*, 35:224-231, attached as Exhibit **D**).

Further, some vaccines aimed at protecting against chronic infection of HCV or to ameliorate hepatitis are currently in phase I/II testing (Houghton *et al.*, 2005, *Nature* 436: 961-966, see Tables 2 and 3, attached as Exhibit **E**). In addition, Houghton *et al.* teaches that it will also be important to understand the mechanisms involved in immune dysfunction and evasion during chronic HCV infections so as to facilitate the design of further immunotherapies (Houghton et al., Id. See lines 1-3, left column, page 965).

Therefore, based on the state of the art as confirmed by the enclosed references, it is respectfully submitted that one skilled in the art would acknowledge that a vaccine inducing a CTL response in a host can be used a therapeutic vaccine against HCV from those prior arts and thus, applicants believe that the instant application complies with 35 U.S.C. 112, first paragraph.

For all of the above reasons, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

C. The rejection under 35 U.S.C. 102(b)

At page 5 of the Office Action, the Examiner has maintained the previous rejection of pending claims 1, 2, 6, 16, and 21 under 35 U.S.C. 102(b) as allegedly anticipated by Saito et al. (US Patent 5,731,172) and separately, byTang et al. (US 200410166488 Al). At the top of page 6 of the Office Action, the Examiner states that,

> [i]n response to Applicant arguments the Office notes that the present claims recite an open claim language with regard to the components of the DNA vaccine. Therefore the claims, as amended read on a DNA vector comprising DNA encoding El, E2, NS3, NS4 and NS5 proteins. Because both the Saito's and Tang's constructs comprise DNA encoding El, E2, NS3, NS4 and NS5 proteins, Tang and Saito anticipate the present claims.

Applicants respectfully disagree. Pending claims 1 and 16 are amended to replace the term "containing" by "consisting essentially of." Thus, the first, second and third plasmids of claims 1 and 16, each plasmid taken separately, cannot contain the additional elements described by Saito et al. and Tang et al. This is in addition to the points of distinction over the two respective cited references that were noted in the previous response (November 26, 2007) and incorporated by reference herein. It is submitted that the instant claims clearly avoid Saito et al. and Tang et al. references.

For all of the above reasons, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

D. Fees

Three new dependent claims are added. No additional claim fee is believed to be due, because a total of 37 claims were originally paid for, and the total number of claims is now 36, in view of the previous cancellation of claims 3 and 18, and the present cancellation of dependent claims 36 and 37. Nevertheless, if it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275.

This response is being filed with a petition for a three-month extension of time and a Request for Continued Examination (RCE) together with the required **Large Entity** fees via credit card authorization. No further fee is believed to be due. If it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275.

It is now believed that the Applicant no longer qualifies for small entity status, so that all fees paid are based on the Large Entity fee tables.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

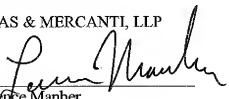
E. Conclusion

In view of the actions taken and arguments presented, it is respectfully submitted that each of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

LUCAS & MERCANTI, LLP



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